



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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CLEARINGHOUSE RULE 05-078

Comments

[NOTE: All citations to “Manual” in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated January 2005.]

2. Form, Style and Placement in Administrative Code

a. Item 9 (“Analysis and supporting documents used to determine effect on small business or in preparation of economic impact report”) is missing from the 12 items that should be included in the rule summary. [See s. 1.02 (2), Manual.]

b. Over seven pages of the proposed rule consists of copies of rules in Iowa, Illinois, Michigan, and Minnesota for the “Comparison with rules in adjacent states” item of the summary. Summaries of those rules would facilitate the ability of a reader to compare them with the proposed Wisconsin rule.

c. On page 12, the “Effect on small business” section of the rule states that the “proposed rules will be reviewed” to determine whether they will have a “significant” economic impact on a “substantial” number of small businesses. However, if the rule will have any effect on small business, that should be stated in this section and the phrase “and affecting small business” should be included in the relating clause. [See s. 1.02 (1), Manual.]

3. Conflict With or Duplication of Existing Rules

a. No reference is made in the rule to s. Phar 7.08, “Prescription orders transmitted electronically,” although it appears to duplicate, and in at least one instance conflict with, the requirements for transfer of prescription order information by computer system addressed throughout s. Phar 7.055. Section Phar 7.08 (1) states that prescription orders transmitted by fax are not considered electronic prescription orders, and authorizes prescription orders to be

transmitted electronically “via computer modem or other similar electronic device.” Section Phar 7.055 (4) adds a requirement that a “computer system” used for transmitting prescription order information “contain a common central processing unit electronically sharing a real-time, on-line database.” This requirement for a “common central processing unit” appears to conflict with s. Phar 7.08 (1), which allows transmission via computer modem over the internet. In any case, it appears that s. Phar 7.08 should be incorporated into s. Phar 7.055 so that all requirements for electronic transmission of prescription order information are reconciled and available in one rule provision.

b. The text to what is renumbered as s. Phar 7.05 (1) (intro.) in the draft rule does not correspond to the text for s. 7.05 (6) (intro.) in the current rule following the word “record.”

5. Clarity, Grammar, Punctuation and Use of Plain Language

a. Section Phar 7.055 (1) (intro.) would be clearer if it used the active voice and the sentence was changed to: “A pharmacist may transfer prescription order information between pharmacies licensed in this state or another state, for the purpose of original or refill dispensing, if all of the following conditions are satisfied:”. In pars. (1) (a), (e) and (f), “shall be” should then be changed to “is.” Par. (b) should be restated as follows: “A computer system used to record a verbal transfer of prescription order information for a non-controlled substance meets the requirements of s. Phar 7.05 (1) (a) and (b).” In par. (c), “shall record” should be changed to “records.” In par. (d), “shall be” should be changed to “are.”

b. In s. Phar 7.055 (1) (f), “they perform” should be changed to the singular “he or she performs.”

c. In s. Phar 7.055 (2) (a) 1., the word “on” should be inserted before “a prescription.” In subd. 2., “it” should be replaced with “the prescription order.”

d. In s. Phar 7.055 (3) (b), (c) (intro.), and (d) (intro.), a comma should be inserted after “used.”

6. Potential Conflicts With, and Comparability to, Related Federal Regulations

In s. Phar 7.055 (3) (c) (intro.) and (d) (intro.), the exception provided by the phrase “Unless a computer system meeting the requirements of sub. (4) is used” appears to conflict with federal regulations [21 CFR 1306.25 (a) and (b); see pp. 2 and 3 of the rule], which do not provide such an exception to requirements for what the transferring pharmacist and the receiving pharmacist record.